

EXH
A

District Court, S.D. New York

Griesa, J.

North American Vaccine Inc. v. American Cyanamid Co.

No. 91 Civ. 1449 (TPG)

Decided September 9, 1992

PATENTS

1. Patent construction — Claims — Defining terms (§125.1305)

Phrase, in claim for vaccine, "a terminal portion of the polysaccharide," means linkage only at one terminal portion of polysaccharide, or monofunctionality, rather than linkages at both ends, even though inventor testified that he did not intend patent to be limited to monofunctionality, since patent language itself, although not using word "monofunctionality," conveys that intent, and does not indicate any broader claim.

2. Patent construction — Claims — Defining terms (§125.1305)

"Conjugate," in claim for vaccine which refers to "comprising the conjugate," refers to mixture consisting of various molecules which are produced and not to molecule itself.

3. Infringement — Construction of claims (§120.03)

Patent claims for vaccine must be interpreted to define monofunctional substance, meaning linkage only at one terminal portion of polysaccharide, and are thus not infringed by defendant's "HibTITER" vaccine, which involves difunctional substance.

Particular patents — Chemical — Vaccines

4,356,170, Jennings and Lugowski, immunogenic polysaccharide protein conjugate, not infringed.

Action by North American Vaccine Inc., et al., against American Cyanamid Co., et al., for patent infringement. Judgment for defendants in bench ruling.

John Diaz and Arnold I. Rady, of Morgan & Finnegan, New York, N.Y., for plaintiffs.

Donald R. Dunner, Brian B. Brunsvold, and Thomas W. Banks, of Finnegan, Henderson, Farabow, Garrett & Dunner, Washington, D.C.; Daniel J. Thomasch, of Donovan Leisure, Newton & Irvine, New York, for defendants.

I'd like to now put my findings and conclusions on the record, and I do that with this preface:

This has obviously been a long and complicated case, and I'm sure that it might appear foolhardy to try to render a bench decision. But for me what is important is to make my ruling while I have in my mind, and fresh in my mind, the benefit of all the hard work that has gone on by the lawyers and all the rather vigorous interchanges that have gone on between me and the lawyers.

Now, I'm going to put down on the record with the court reporter my findings and conclusions.

After that, the parties can see the transcript, and if they have any feelings about something that is left out that hasn't been covered, they can request an amendment of the findings. But all that process will be over with, I would say, within a week, and I think a lot is to be gained by doing it this way.

I do not intend to discuss all the evidence. I do not intend to discuss the pros and cons and significance of even a substantial part of the evidence. What I am going to do is to make my findings and my conclusions with some relatively brief explanation.

I have been furnished with legal authorities, both at the beginning of the trial and at various points through the trial, and I have considered the relevant authorities, although I do not intend to cite them specifically in this statement.

Now, let me repeat what I have indicated before, and that is that the case has been presented in the most remarkable manner. The skill and thoroughness and fairness and courtesy of all the participants have been an absolute model. The examination and cross-examination, all those things have done their job. It wasn't a wasted effort in any way.

And certain of the attorneys have been spokesmen for their clients, but obviously there has been a lot of very hard work by the staff that helped those attorneys, and all of that has produced a trial with very fine organization and elucidation of the subjects.

I think the case is a close one. That means that the plaintiffs have powerful points in their favor. Those points have been expressed with great weight by Mr. Diaz and his colleagues. The defendants have powerful arguments in their favor. Those arguments have been expressed by the attorneys for the defense.

The decision has to be made, and I believe that the scales tip, not drastically, but I think they tip in favor of the defense.

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The case, of course, involves patent number 4,356,170. The application was filed May 27, 1981. It was issued October 26, 1982. The principal inventor is Harold J. Jennings of Ottawa, Canada. Also listed as an inventor is Mr. Czeslaw Lugowski.

The plaintiffs are North American Vaccine, Incorporated, and National Research Council of Canada. The suit is a claim for patent infringement. It is brought against American Cyanamid Company and Praxis Biologics, Inc.

The patent relates to certain technology involved in vaccines. Neither Dr. Jennings, nor the other inventor, nor the plaintiffs have actually produced a vaccine or any product based on the patent. However, Cyanamid and Praxis have produced a vaccine called HibTITER, which is intended to deal with a particular kind of meningitis. That vaccine is highly successful, and the claim is that that vaccine infringes certain claims of the '170 patent, specifically, claims 12 and 25.

The question which has been involved in most of the evidence and argument of this trial is the question of interpretation of claims 12 and 25.

I think it is safe to say that if claims 12 and 25 were to be interpreted in accordance with plaintiffs' position here, it would not be difficult to find infringement.

So the basic question upon which the infringement issues depend is how should we interpret claims 12 and 25. Since this is an infringement case, and the plaintiffs have the burden of proof on infringement, I believe it is safe to say they have the burden of proof to show their particular interpretation, as that is foundational to the infringement issue.

Now, claim 12 and claim 25 are both dependent upon claim 11, and it is necessary to read into the record claim 11, which is as follows:

"An antigenic-polysaccharide:protein conjugate wherein the polysaccharide and protein are covalently linked through a CH₂-HN-protein linkage to a terminal portion of the polysaccharide without significant crosslinking, said antigenic polysaccharide having a MW above about 2,000."

Now, claim 12 reads as follows:

"The conjugate of claim 11 wherein the antigenic polysaccharide is selected from the group derived from meningococci, Haemophilus influenza, pneumococci, B-hemolytic, streptococci, and E. coli."

Claim 25 reads as follows:

"A human infant vaccine comprising the conjugate of claim 11 wherein the polysaccharide comprises at least one of

meningococcal polysaccharide and Haemophilus influenza polysaccharide."

Now, although claim 11 is not literally referred to in the infringement cause of action, it is foundational and its interpretation is crucial to a resolution of this case.

There are several issues about the meaning of claim 11. One is what is meant by the word "conjugate". I'll come back to that later. The most serious issue relates to the phrase "a terminal portion of the polysaccharide without significant crosslinking." The phrase "a terminal portion" is, of course, in the singular.

The defense contends that this singular phrase should be interpreted as just that: as providing for linkage at one terminal portion of the polysaccharide. This is a crucial point because the vaccine produced and marketed by defendants involves the use of polysaccharides, which have linkages at both terminal portions at both ends.

A polysaccharide can be viewed as being a string. A string has two ends. HibTITER has the chemical linkage at each end, at both ends, at both terminal portions. Thus, it is crucial to defendant's case to urge upon the Court that the language in claim 11 should mean literally what it says: that it is a claim in which there is to be linkage at one terminal portion of the polysaccharide, not at both ends, not at each end.

There was extensive evidence at the trial about the background of Dr. Jennings' invention, the technology which existed at the time of his invention, the problems in the immunization of people who were sought to be immunized against certain diseases.

The polysaccharide was known to be important in creating the kind of vaccines that Dr. Jennings and other scientists were working on. There were various problems in the use of these polysaccharides. One of these problems was the question of how the polysaccharide would be introduced into the system of the person being vaccinated or immunized, and the focus of the particular work was upon infants, very small infants.

Their needs as far as immunization were different from older children and from adults, and the evidence in this case indicates that one way, and perhaps the only way, but at least one way of getting the polysaccharide introduced into the system of the infant was to have it linked to a protein, or perhaps more than one protein, and the protein would carry out the job of getting it into the system of the infant. And that is why claim 11 talks about linking a protein to a polysaccharide.

Now, some of the work in this field involved methods which placed a great deal of protein matter on the polysaccharide, that

protein matter being distributed all along the length of the polysaccharide. The problem with this was that there was too little polysaccharide left exposed, and I think the evidence refers to this problem as being that the immune system of the infant would not recognize the polysaccharide. In any event, covering the polysaccharide with protein or having a lot of protein along the length was a problem.

As we know from the evidence in this case, that which I have just called a problem perhaps was not perceived by everyone as a problem, because certain parties developed products in which this situation occurred where there was protein distributed along the length of the polysaccharide. But at least to some scientists it was viewed as a problem, and certainly it was viewed as a problem by Dr. Jennings.

If we just stepped away from the chronology of the developments and thought in an abstract way, we might say that the issue of having protein distributed along the length of the polysaccharide might be solved if the protein were placed at one end of the polysaccharide, or, in the language of claim 11, at a terminal portion of the polysaccharide.

Again, speaking somewhat abstractly, one might say that the problem of having protein distributed along the length of the polysaccharide might be solved by having protein distributed at the two ends, the two terminal portions, provided that the protein was not massive or the polysaccharide was not so short that this somehow obscured the polysaccharide.

But given proper proportions of the polysaccharide and protein, it is not difficult to conceive of the issue under discussion as being taken care of by a polysaccharide having a protein at one end or having a protein at two ends.

Now, it is time to mention the issue of cross-linking. Cross-linking refers to a situation where a polysaccharide acts as a link between two proteins. If proteins are located all along the length of a polysaccharide, there are many cross-links. Each space on a polysaccharide between two proteins is a cross-link.

There are other ways in which cross-linking can come about creating structures that look like networks. This results in what some perceive as a problem in defining the exact structure.

If there is a great deal of cross-linking and different kinds of networks, the definition of the substance, the definition of the molecular shape becomes more and more vague and more and more diffuse. Cross-linking also

affects the solubility. The more cross-linking, the less solubility.

It is a fact established in the evidence that where a polysaccharide has a protein linked at one end, there is no cross-linking. You can have several polysaccharides linked to one protein, but none of those polysaccharides are linked to two proteins, and thus there is no cross-linking.

When you have polysaccharides with proteins all along the backbones, there is abundant cross-linking. Where you have polysaccharides with proteins at the two terminal ends, there is less cross-linking than in the situation just mentioned, but there still will develop, as illustrated in the evidence in this case, a substantial amount of cross-linking.

Now we come back to the question of interpretation. Plaintiffs contend that the singular phrase "a terminal portion of the polysaccharide" is a kind of generic term and it is not intended and should not be interpreted to be limited to one single terminal portion. It should be interpreted to refer to a terminal portion at one end and also a terminal portion at the other end where there is such a thing.

In effect, plaintiffs wish to have the claim 11 language interpreted to mean a terminal portion of the polysaccharide at one or both ends.

As I have indicated, the defense position is that the claim 11 language means what it says, and refers only to a single terminal portion.

Now, as I've said many times during the trial, we cannot solve this problem by staring at the language and simply saying there is a singular indefinite article and a singular noun and that is that. It is perfectly possible, as an initial proposition, that the phrase "a terminal portion" is a generic term and could mean exactly what plaintiffs say it means.

In order to solve the problem, we need to look at some of the other evidence that can be considered properly under the law on the question of interpretation. We, of course, need to look at the other portions of the patent: the summary of the invention; the description of the experiments; other claims besides 11, 12 and 25. In other words, the whole patent.

In addition, there has been the testimony by the inventor, Dr. Jennings, and there has been discussed in the evidence at great length an article Dr. Jennings wrote in 1981 which was given by him to the drafter of the patent. That is Defendants' Exhibit F. Also referred to in our discussion of the case is a talk given by Dr. Jennings at the National Institute of Health in the fall of 1980, which talk was embodied in an article which came

ability. The more cross-linking, the more rigidity.

Established in the evidence that polysaccharide has a protein linked to it, there is no cross-linking. You can have polysaccharides linked to one of those proteins, and thus there is no cross-linking.

When you have polysaccharides with proteins at the two terminal ends, there is cross-linking. Where you have polysaccharides with proteins at the two terminal ends, there is less cross-linking than in the case mentioned, but there still will be cross-linking. As illustrated in the evidence in this case, the amount of cross-linking is not the same. Plaintiffs contend that the use of "a terminal portion of the molecule" is a kind of generic term and should not be interpreted to refer to one single terminal portion. It should be interpreted to refer to a portion at one end and also a terminal portion at the other end where there is cross-linking.

Plaintiffs wish to have the claim interpreted to mean a terminal polysaccharide at one or both ends.

As indicated, the defense position is that the language means what it says, and refers only to a single terminal portion.

As we said many times during the trial, to solve this problem by staring at the language and simply saying there is a difference between a finite article and a singular is that. It is perfectly possible, in a legal proposition, that the phrase "a terminal portion" is a generic term and could mean what plaintiffs say it means.

To solve the problem, we need to look at the other evidence that can be used to interpret the language properly under the law on the interpretation. We, of course, look at the other portions of the summary of the invention; the description of the experiments; other claims in the patent; and 2 and 25. In other words, the

entire case, there has been the testimony of Dr. Jennings, and there has been evidence in the evidence at great length. Dr. Jennings wrote in 1981, and by him to the drafter of the Defendants' Exhibit F. Also our discussion of the case is a summary of Dr. Jennings at the National Institute of Health in the fall of 1980, which was included in an article which came

out in 1982. This article is Defendants' Exhibit CT.

There is various other evidence relevant to the question of interpretation, including lengthy testimony by an expert called by plaintiffs, Dr. Harry Schoolnik of Stanford. I will not try to name all the witnesses, I will not try to summarize all their testimony, but there has been a substantial amount of testimony and documents received into evidence bearing on the question of interpretation.

Perhaps the most important point in the evidence is the fact which is established without question, that is, that the laboratory work carried out by Dr. Jennings leading up to the patent was specifically designed to produce polysaccharides with protein linkage at only one end of the polysaccharide, that is, at one single terminal portion.

In this work, it was not a matter of indifference to him whether one or two terminal portions were involved.

The testimony of Dr. Jennings, particularly on cross-examination, involved admission after admission about his desire in his experimentation to achieve what he called monofunctionality, which is another word for having the linkage at one end of the polysaccharide. He explained that he was doing this as a chemist, and he wanted a clear-cut chemical solution to the issues which I mentioned earlier. He wanted the clearest possible definition for the substance that he was creating. And therefore, he conducted experiments with the desire and the purpose of producing monofunctionality, that is, linkage at one terminal portion. This meant that cross-linking would be entirely avoided.

The only exception to this was that he knew that he might not be able to avoid some cross-linking because of some attachment of proteins at places other than the one terminal end, but this was something that would not come about by design, but only because in the world of chemistry, absolute purity might not be achieved. But he sought, as he has admitted, the monofunctionality, which gave the best definition for the substance since it did not involve cross-linking.

This was made clear in his National Institute of Health speech and in the article he wrote in 1981. The speech and the article presented essentially the same concepts, described essentially the same experiments and described the same goals. For instance, in the article, he states as follows: "We have tried to extend the monofunctional group approach used in conjugating oligosaccharides to the larger molecular size meningococcal polysaccharides."

Later in the same article he states, "The ideal situation would be to specifically introduce one of these functional groups per polysaccharide molecule, preferably located in a terminal position."

Still later in the same article, he talks about monovalent polysaccharide molecules.

Let me say that where he speaks of functional groups, what is being talked about is a group not in the sense of one protein linked at one end and another linked at another end. But the group is a reference to a group of atoms, hydrogen, oxygen, and carbon.

Another expression that has been used at the trial is the word aldehyde, again referring to this grouping of the hydrogen, oxygen, and carbon atoms.

Now, there is simply no question about the fact that if the language of the 1981 article and of the NIH speech had been literally carried over into the patent, we really would have no issue here. It would be crystal clear that the patent related to monofunctionality. That is the idea of the linkage being at the one terminal portion of the polysaccharide. There really would be no problem with interpretation that anybody could sensibly raise.

However, the patent does not carry over the literal language of the NIH speech or the 1981 article. It does not use the word monofunctionality. It does not use the word monovalence. It does not literally say that Jennings is trying to achieve one functional group. However, on some crucial points, certain language of the article and of the NIH speech are carried over into the patent and what has occurred is something which is rather odd in light of plaintiffs' contentions and Jennings's testimony here.

Jennings testified that when it came to taking out his patent, he intended to claim something broader than what he talked about in his speech and his article. He has testified that he did not intend his patent to be limited to monofunctionality. He has testified that his intent was to cover where the terminal linkage occurred at both ends of the polysaccharide.

Now it is clear that in the article and the speech, he was not talking about terminal portions at two ends, or what we call difunctionality. But he says when it came to drafting the patent, he intended to have his patent drafter broaden out his claims to cover the two terminal end situations.

And as already stated, he points to the fact that the word monofunctional and the word monovalent, those words are not present in the patent. The problem is that in some crucial respects, although he has left out those particular words, he has carried over other descriptive wording which was in the

article and the speech which were tied in with the use of those words, monofunctional and monovalent. Thus, in the patent, those particular words are left out, but the descriptions which develop the concept of monofunctionality are carried over into the patent.

An example of this, I think, is worth reading, and I will do so. On page 1012 of the article he states, "We have tried to extend the monofunctional group approach used in conjugating oligosaccharides to the larger molecular size meningococcal polysaccharides. This was achieved by the introduction of a terminally located free aldehyde group into the polysaccharide molecules through which they could be specifically coupled to protein without activating the other functional groups on the polysaccharide. This procedure avoids cross-linking, minimizes the possibility of extraneous chemical modification of the polysaccharides, and results in better-defined immunogens."

Now, in the summary of the invention contained in the patent, we have wording which is very, very close to the wording in that article and contains most of the language which was obviously designed in the article to convey and elaborate upon the monofunctional approach. However, in the patent, and the language I will just read now, the word monofunctional is not there.

Thus, the patent states, and I'm reading from column 2, beginning at line 33: "We have found it possible to introduce a free aldehyde group into the polysaccharide molecule in a terminal location and to specifically couple this aldehyde group to protein without activating other functional groups on the polysaccharide. This procedure avoids cross-linking and extraneous chemical modification of the bulk of the polysaccharide resulting in better-defined immunogens."

Now, that language, in substance, and almost verbatim form, was in the article. Obviously in the article it was inexorably linked to the concept of monofunctionality. However, in the patent, although the word monofunctional was omitted, the attending language, which was an elaboration of the monofunctional idea, was carried over into the patent.

Now, anyone reading the patent will find over and over again references which talk about the single terminal group. I don't think the word single is used, but the singular usage is over and over again presented. I don't think any purpose would be served in reading all those references; but let me just set down a few of them.

The first two lines of the patent refer to a terminally located aldehyde group. That, of course, is in the singular, and as I have

stated, group does not talk about linkage at two ends. It talks about a group consisting of three types of atoms. Sometimes instead of saying aldehyde group, we say aldehyde. It is in the singular. In column 2, line 61, there is a reference to linkage to a terminal portion. That language forecasts the language of claim 11. Column 3 refers to a terminal portion of the molecule. And of course, we come to claim 11, which has that same language, a terminal portion of the polysaccharide. There are many other references which can be easily found with the same kind of wording.

Thus, again, what happened was that the concept of the speech and article was carried over into the patent. It is true that words such as "monofunctional" were not there, but all the other attendant wording is there.

Now, the question naturally presents itself. If Dr. Jennings sought to broaden his patent beyond what was contained in the article and the speech, why did he not express this intention? If his intention was to have a patent on the production of aldehydes at both terminal ends, this is something that can be easily expressed in the English language, and clearly expressed. If he desired to depart from the objectives that he so clearly had in his experimentation described in his article and his speech, if that was his purpose, surely that was something that he thought about, it wasn't just chance, and he would want to think about how to express it.

He did not express it. And that is the basic reason why I am holding in favor of the defendants on the question of interpretation. There are ample means through simple devices of wording to convey what he claims was his intention. He simply did not do it.

[1] My ruling is that the wording in claim 11, "a terminal portion," should be interpreted to refer to monofunctionality, and that is the way I am interpreting it.

Now, we come to the phrase "without significant cross-linking." There is some indication in plaintiffs' arguments that there was an intention along with incorporating this difunctional approach into the patent to provide for cross-linking because it has certain legitimate chemical benefits, although it does indeed have some detriments.

But there is nothing in this patent affirmatively teaching anything about achieving cross-linking. There is nothing in the patent except a negative view of cross-linking.

The proper interpretation is that the phrase "without significant cross-linking" was inserted simply to cover the possibility that I've earlier described, that in the chemical process, one cannot be assured of absolute purity, there may be some cleavage and

talk about linkage at a group consisting of sometimes instead of we say aldehyde. It is in line 61, there is a terminal portion. The language of refers to a terminal. And of course, we have that same language of the polysaccharide references which the same kind of

opened was that the article was carried it is true that words "al" were not there, but the wording is there. It naturally presents it ought to broaden his as contained in the why did he not express his intention was to production of aldehydes is something that in the English language. If he desired to say that he so clearly described in his that was his purpose something that he just chance, and he it how to express it. And that is the basic in favor of the of interpretation. through simple de-ey what he claims ply did not do it. e wording in claim should be interpret-nality, and that is it.

phrase "without There is some in-ments that there with incorporating into the patent ecause it has cer-nefits, although it riments. his patent affirma-about achieving ing in the patent cross-linking. ion is that the nt cross-linking" er the possibility that in the chemi-assured of abso-me cleavage and

some proteins appearing in places that were not intended, and the patent is designed to cover that situation.

[2] This brings us to the final point about claim 11, and that is what is meant by the word "conjugate." Plaintiff contends that conjugate refers to the molecule itself. The defense contends that it refers to the mixture consisting of the various molecules which are produced. Conjugate is referred to many times in the patent. Judging from the patent as a whole, it is quite clear that conjugate in claim 11 means the mixture and not the single molecule. This is also made clear by the testimony of Dr. Jennings himself.

On the overall issue of interpretation, plaintiffs' expert witness, Dr. Schoolnik, gave very interesting testimony. He testified that if he looked at the language of the patent and the background that I've described, he would say that it only covered monofunctionality. And the only reason he could voice an opinion in favor of difunctionality — that is, covering the production of two terminal linkages at the two ends of the polysaccharide — was that there is a reference in claims 12 and 25 and one or two references in the other portions of the patent to Haemophilus influenza. He said that the Haemophilus influenza polysaccharide, at least the one that was best known in this field of technology, would necessarily yield aldehydes at the two ends. And therefore, this reference in claim 12 and claim 25 and one or two other places drives the interpretation of the entire patent so that claim 11 covers, the whole patent covers one or both terminal portions. It covers monofunctionality and it covers difunctionality.

I really cannot accept this proposed method of interpretation. This patent has a great deal of discussion of experimentation and theory, and it is all referring to this monofunctional approach. To allow all of that weight, really massive weight of discussion, descriptions of experiments and so forth, to be cancelled out by the two words "Haemophilus influenza," in my mind, would not be a fair method of interpretation.

Other points need to be made about claims 12 and 25. Claim 12 refers to five different groups or families of bacteria with polysaccharides. And each of those families has numerous, what are called serotypes. It has been stipulated that if the Jennings oxidation process were applied to all of these serotypes of the five groups referred to in claim 12, some would produce a monofunctional result. Some would produce a difunctional result. Some would produce a polyfunctional result; that is, protein distributed all along the polysaccharide.

And I think it is clear from the record that on some of these serotypes, it is not known what would happen. In addition, it is stipulated that on some of these serotypes which would not naturally and easily yield the monofunctional result, such a result could be obtained if there was pretreatment of the kind taught at an earlier point in the patent.

Now, as for Haemophilus influenza, this is a family or group which has five or six serotypes. Haemophilus influenza B is the one which yields the difunctional result if the Jennings type oxidation is used and if it is controlled in a way which is appropriate to Haemophilus influenza.

Plaintiffs admit that much of what is referred to in claim 12 would not be appropriate for the Jennings patent, that is, the situations where proteins are distributed all along the backbone, the polyfunctional result. Plaintiffs deal with this by saying that these situations should be read out of claim 12. They should be rejected, ignored.

The question is: What do you do with Haemophilus influenza B? In my view, the same thing should be done about Haemophilus influenza, as with the polyfunctional polysaccharides. The question should be: What is the main teaching of the patent? Does the patent, prior to claim 12, teach a difunctional result? Claim 12 and also claim 25 derive from claim 11, and obviously stem from the whole body of the descriptive material in the patent. In my view, it is improper to ignore that in respect to Haemophilus influenza any more than for the serotypes where polyfunctionality occurs. Difunctionality is simply not taught by the bulk of the descriptive material in this patent. It's not specifically taught in claim 12 or claim 25. All that we have is some alleged implication of a difunctional result resulting from the phrase Haemophilus influenza, allegedly known to scientists who know the necessary chemistry. This is far from teaching difunctionality in clear language in a patent.

There has been an argument that claims 12 and 25 are invalid because there are so many different kinds of polysaccharides referred to which would yield different results, polyfunctional, difunctional and monofunctional, some of which results are admittedly contrary to the patent's teaching.

In other words, the contention of the defense is that claims 12 and 25 are invalid because they really don't teach anything that is definite, or define anything that is sufficiently definite in accordance with Section 112 of the patent law. I agree with that contention, and I hold that claim 12 and claim 25 are both invalid on the ground asserted by the defense. In the alternative,

even if they are to be deemed valid, I hold that there is nothing in either claim which can be properly interpreted to define a difunctional result contrary to claim 11 and the teaching of the patent as a whole.

[3] What I have ruled as far as the interpretation issues dictates the result of the infringement claim. Since the proper interpretation of the patent, including claims 12 and 25, is to define a monofunctional substance, defendants' product HibTITER cannot be held to infringe because it involves a difunctional substance.

Plaintiffs have one alternative argument about infringement which must be dealt with. They contend that even if defendants prevail on their basic interpretation arguments, still there is infringement. They contend that there is in HibTITER a certain amount of monofunctionality involved in the so-called monomers which constitute a portion of the molecules in the product.

This argument largely depends on the meaning of the word "conjugate" in claim 11. They argue that "conjugate" refers to the molecule, so a single molecule could be an infringing molecule. I reject that interpretation, as I have said, and have ruled that "conjugate" refers to the mixture.

But even as to the individual molecules, there is no showing that the HibTITER contains any truly monofunctional polysaccharides. Defendants' process creates cleavage through oxidation. The polysaccharide fragments which result have aldehydes at each of the two ends.

There are situations, apparently, where only one of those aldehydes links up to a protein, and indeed there apparently are many of those situations. But this is not because they do not have an aldehyde created at both ends. It is because, by chance, only one aldehyde links with a protein and, in a further portion of the chemical process, the other end becomes capped.

But more importantly, "conjugate" refers to a mixture, and the mixture, in order to be within claim 11, and therefore, within claims 12 and 25, must be without significant cross-linking. The evidence is overwhelming that the mixture involved in HibTITER has very substantial cross-linking.

A high proportion of the molecules are what are called dimers or trimers, and these molecules involve cross-linking to a significant degree. Therefore, there is no infringement even on this alternative theory suggested by plaintiffs.

For the above reasons plaintiffs' complaint is dismissed.

And so that concludes our proceedings. Thank you.

District Court, S.D. Florida

Rally Manufacturing Inc. v. Mr. Gasket Co.

No. 87-1533-CIV-MISHLER

Decided June 12, 1992

JUDICIAL PRACTICE AND PROCEDURE

1. Procedure — New trial; directed verdict; JNOV (§410.30)

Trademark infringement plaintiff's deliberate failure to reveal its employment negotiations with defendant's former employee, who was called as defendant's chief witness but who then testified that reasonably prudent consumer would have confused defendant's "Signature Series" packaging with plaintiff's "Designer Series," warrants order pursuant to Fed.R.Civ.P. 60(b)(3) vacating \$10 million judgment won by plaintiff, despite overwhelming evidence of trade dress infringement, since plaintiff's misbehavior prevented defendant from demonstrating to jury that witness's testimony was tainted by his affiliation with plaintiff, and since plaintiff's attorney, during closing arguments, not only failed to reveal that witness was soon to be hired by plaintiff but characterized witness as "neutral."

Action by Rally Manufacturing Inc. against Mr. Gasket Co. and American Automotive Marketing Inc. for trade dress and trademark infringement. On defendant's motion to vacate judgment and for new trial. Motion granted.

Abbey L. Kaplan and Steven I. Peretz, of Kluger, Peretz, Kaplan & Berlin, Miami, Fla., for plaintiff.

Kenneth R. Umans and Frances H. Weber, of Colucci & Umans, New York, N.Y. (Harley Tropin, of Kozyak, Tropin, Throckmorton & Humphreys, Miami, of counsel), for defendant.

Mishler, J.

Defendant Mr. Gasket Company, ("Gasket"), moves pursuant to Fed. R. Civ. P. 60(b)(3) to vacate a judgment of this court, entered April 17, 1991, awarding plaintiff Rally Manufacturing, Inc. ("Rally") \$10,013,500.00 in damages in its action for trade dress and trademark infringement. For the reasons stated herein, defendant's motion

for relief from judgment and for a new trial is granted.

BACKGROUND

Rally and Gasket are manufacturers and designers of automobile accessories. On September 8, 1987, Rally filed a lawsuit against Gasket alleging that the trade dress packaging used in its "SIGNATURE SERIES" product line unlawfully infringed on the trade dress packaging used by Rally in its "DESIGNER SERIES."

On March 21, 1991, the jury awarded Rally \$10,013,500.00 in damages attributable to: (1) trade dress and trademark infringement (\$5,715,500.00) (2) recovery of Gasket's profits (\$298,000.00) and (3) punitive damages for unfair competition (\$4,000,000.00).

Gasket now argues that the judgment entered in Rally's favor should be vacated because it was procured through "fraud, misrepresentation or other misconduct." Fed. R. Civ. P. 60(b)(3). The heart of Gasket's Rule 60(b)(3) motion centers on the testimony of one William Hyatt ("Hyatt").

Hyatt was the Vice-President in charge of Gasket's automobile accessory group from July or August of 1986 until he terminated his employment in January of 1988. While working for Gasket, Hyatt authorized the marketing and packaging of Gasket's "SIGNATURE SERIES" line of automotive accessories. On the day of trial, Hyatt testified that a reasonably prudent consumer would have mistaken Rally's "DESIGNER SERIES" for the "SIGNATURE SERIES."

Gasket's attorney, Michael A. Painter, Esq., ("Painter") was shocked by Hyatt's testimony. Hyatt had cooperated extensively with the defense prior to the trial and made it very clear that he would testify that it was unlikely that a reasonable consumer would confuse the "SIGNATURE SERIES" product line with Rally's "DESIGNER SERIES."

In light of Hyatt's past cooperation, Painter assumed that he would testify on Gasket's behalf. After all, Hyatt had persuaded Gasket to retain Painter as trial counsel. Hyatt had known Painter for almost twenty years and told Gasket that he was "somebody that I could trust."

The two men had numerous conversations and meetings about the general strategy that Gasket would employ to defend the case. Painter centered Gasket's defense around Hyatt's testimony.

¹ March 23, 1992 Deposition of William Hyatt ("Hyatt Deposition") p. 33.

During the course of their many discussions, Painter prepared Hyatt for the type of questions he would face during the trial.² Hyatt was provided with a copy of his deposition along with an outline of his proposed testimony. As a result of these comprehensive discussions, Hyatt became aware of virtually all of the evidence that Gasket planned to present at trial.

Based on the above stated facts, it seemed obvious to Painter that Hyatt would testify on Gasket's behalf.³ However, shortly before the trial began, Painter learned that Rally intended to call Hyatt as a "hostile" witness. While Painter was somewhat puzzled by this revelation, he nevertheless continued to adhere to his belief that Hyatt's testimony would be favorable to Gasket.

What Painter did not know was that Hyatt and Rally had entered into an employment agreement that was all but finalized prior to the trial. This agreement was the culmination of close to three years of negotiating. The only detail that needed to be resolved was Hyatt's actual starting date. Rally would not allow Hyatt to start working until the *Rally-Gasket* litigation had ended. As a result, Hyatt began working for the company a mere three days after judgment was entered against Gasket. Rally, through its attorneys, Abbey L. Kaplan, Esq. ("Kaplan") and Steven I. Peretz, Esq. ("Peretz") deliberately concealed this information from Gasket.⁴

EMPLOYMENT NEGOTIATIONS BETWEEN RALLY AND HYATT

Rally and Hyatt conducted intense employment negotiations between 1988 and 1991.⁵ Throughout the course of these discussions, Rally made it clear that the starting date of Hyatt's employment would be

² On one occasion, they met for two hours at Hyatt's house, discussed Gasket's trial tactics, and drafted a rough outline of the proposed trial questions.

³ In his affidavit, Painter stated that "[s]ince Mr. Hyatt had been in charge of the group which developed the item which was the subject of the litigation, I had always considered his testimony to be the foundation of Mr. Gasket's defense." (Painter Affidavit p. 6).

⁴ Rally admits in its motion papers that its counsel "had the same knowledge as the company on the status of the Rally/Hyatt employment negotiations." (Plaintiff's Memo. p. 22 n.2).

⁵ Rally did not pursue these negotiations until after its attorneys (Kaplan) issued an opinion letter regarding the effect that an employment agreement would have on the pending litigation with Gasket.

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